

REMARKS

Claims 13-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brine (U.S. Patent No. 5,075,115). Specifically, the Examiner contends that Brine teaches polymers of lactic acid with a molecular weight of 2500-4500, specifies terpolymers with other hydroxycarboxylic acids such as glycolic acid,  $\epsilon$ - caprolactone and valerolactone (column 3, lines 28-32), and discloses glass transition temperatures of 26°C to -65°C (column 3, lines 52-53).

Applicants respectfully traverse that rejection. A terpolymer is a polymer made from three different monomers. As applicants have previously noted, Brine does not teach or describe terpolymers at all, nor does Brine teach lactide-containing terpolymers consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone, as required by claims 13-16. Therefore, the rejection based on Brine is believed to be improper.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The Examiner contends that Brine teaches terpolymers of lactic acid with other hydroxycarboxylic acids. Respectfully, Brine makes no mention whatsoever of terpolymers. Rather, Brine teaches poly(lactic acid) and poly(lactic acid) mixed with copolymers or homopolymers of other hydroxycarboxylic acids. The specification of Brine states that "the present invention is a process for polymerizing lactic acid to poly(lactic acid) . . . the present invention is intended to include the product made by the process as well as copolymers and mixtures of polymers of glycolic acid, valerolactone,  $\epsilon$ - caprolactone,  $\epsilon$ - decalactone, hydroxybutyric acid,  $\beta$ - hydroxyvaleric acid and dioxanone . . ." (see column 3, lines 5-32). Brine's Examples 1 and 2 teach a blend of a poly(DL-lactic acid) polymer and a polycaprolactone polymer, and Table 1, entitled

"Polymer Overview," teaches only poly(L-lactic acid), poly(DL-lactic acid), and polycaprolactone-polymers.

Applicants acknowledge that there is some teaching in Brine of copolymers, but the copolymers taught by Brine are copolymers of lactic acid "with glycolic acid, valerolactone, decalactone, or the like . . . such as racemic lactic acid with glycolic acid, or 1(+)-lactic acid with valerolactone." (Column 4, lines 60-64, emphasis added.) The only copolymers taught by Brine are copolymers that use two different monomers, and these are not terpolymers. There simply is no teaching in Brine to use three different monomers, let alone the particular terpolymers of poly(lactide/glycolide/caprolactone) or poly(lactide/glycolide/valerolactone). A required element of the invention of claims 13-16 is a lactide-containing terpolymer consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone. Respectfully, Brine cannot be said to anticipate claims 13-16.

Furthermore, claims 13-16 specify that the claimed terpolymers exhibit an "adhesive strength of about 600 to about 150,000 Pa" such that they can be used as pressure sensitive adhesives for tissue repair. Brine discloses the use of poly(lactic acid) in dosage forms for the controlled release of pharmaceutically active compounds. Brine is silent on the characteristics of the disclosed poly(lactic acid) compositions. Applicants' claimed polymers are sticky and sticky polymers would complicate (gum up the machine) the tableting of, for example, tableting compositions used to prepare tableted controlled release dosage forms. Further, the polymer compositions taught by Brine (to be used as taught by Brine) necessarily have properties different than the polymers of the present invention. Therefore, Brine cannot reasonably be said to anticipate claims 13-16.

In sum, Brine (U.S. Patent No. 5,075,115) does not describe lactide-containing terpolymers consisting of monomer units selected from the group consisting of lactic acid,

glycolic acid, and caprolactone or valerolactone, nor does the reference describe or suggest such polymers capable of functioning as pressure sensitive adhesives for tissue repair. Brine, therefore, cannot reasonably be said to anticipate claims 13-16. Withdrawal of the rejection of claims 13-16 under 35 U.S.C. § 102(b) is respectfully requested.

Claim 13-18 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner contends that the term "derived" is vague and that it is unclear as to whether derivatives of the recited hydroxy carboxylic acids are intended.

Applicants respectfully note that monomer derivatives of the recited hydroxy carboxylic acids are not intended by this claim language. The language "derived from" was used to be precise. Once the monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone are polymerized, they are no longer monomer units of these hydroxy carboxylic acids. Rather, once polymerized, the units are derived from monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone. Accordingly, the language of claims 13-18 is not vague and applicants respectfully request withdrawal of this rejection.

#### CONCLUSION

The application as amended, is believed to be in condition for allowance. Withdrawal of the rejections and passage of the application to issuance is requested.

Respectfully submitted,



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